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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* GIORGIO TERENGHI, PARI-NAZ MOHANNA, and  
DAVID P. MARTIN

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Appeal 2009-012878  
Application 10/568,649  
Technology Center 1600

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Before ERIC GRIMES, LORA M. GREEN, and JEFFREY N. FREDMAN,  
*Administrative Patent Judges.*  
GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL<sup>1</sup>

This is an appeal under 35 U.S.C. § 134 involving claims to a nerve regeneration device. The Examiner has rejected the claims for obviousness

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<sup>1</sup> The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the “MAIL DATE” (paper delivery mode) or the “NOTIFICATION DATE” (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

and obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

#### STATEMENT OF THE CASE

Claims 1 and 3-6 are on appeal. Claims 1 and 3 are representative and read as follows:

1. A nerve regeneration device comprising a polyhydroxyalkanoate polymer in the form of a porous conduit tube or sheet suitable for nerve repair, the pores in the conduit having a diameter of between five and 500 microns, wherein the polymer comprises 4-hydroxybutyrate.

3. The device of claim 2 wherein the polymer is poly-4-hydroxybutyrate.

The claims stand rejected as follows:

- Claims 1 and 3-6 under 35 U.S.C. § 103(a) based on Hadlock<sup>2</sup> and Martin<sup>3</sup> (Ans. 5);
- Claims 1 and 3-6 under 35 U.S.C. § 103(a) based on Williams '569,<sup>4</sup> Seckel,<sup>5</sup> Schlossauer,<sup>6</sup> and Clavijo-Alvarez<sup>7</sup> (Ans. 7);
- Claims 1 and 3-6 under 35 U.S.C. § 103(a) based on Martin '764<sup>8</sup> or Williams '493<sup>9</sup> or Williams '247<sup>10</sup> or Williams '883<sup>11</sup> or Williams '150<sup>12</sup> or

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<sup>2</sup> Hadlock et al., WO 01/54593 A1, published Aug. 2, 2001

<sup>3</sup> David P. Martin et al., *Medical applications of poly-4-hydroxybutyrate: a strong flexible absorbable biomaterial*, 16 BIOCHEM. ENGINEERING JOURNAL 97-105 (2003)

<sup>4</sup> Williams et al., US 6,548,569 B1, issued Apr. 15, 2003

<sup>5</sup> Seckel, US 5,584,885, issued Dec. 17, 1996

<sup>6</sup> Burkhard Schlosshauer et al., *Synthetic Nerve Guide Implants in Humans: A Comprehensive Survey*, 59 NEUROSURGERY 740-748 (2006)

<sup>7</sup> Julio A. Clavijo-Alvarez et al., *Comparison of Biodegradable Conduits within Aged Rat Sciatic Nerve Defects*, 119 PLASTIC AND RECONSTRUCTIVE SURGERY 1839-1851 (2007)

Williams ‘558,<sup>13</sup> combined with Seckel, Schlossauer, and Clavijo-Alvarez (Ans. 10);

- Claims 1 and 3-6 for obviousness-type double patenting based on the claims of Martin ‘764 or Williams ‘493 or Williams ‘569 or Williams ‘247 or Williams ‘883 (Ans. 12); and
- Claims 1 and 3-6 for provisional obviousness-type double patenting based on the claims of Martin ‘576<sup>14</sup> or Rizk<sup>15</sup> (Ans. 14).

## I.

### *Issues*

The Examiner has rejected claims 1 and 3-6 as obvious in view of Hadlock and Martin (Ans. 5). The Examiner has also rejected claims 1 and 3-6 as obvious in view of Williams ‘569 or Martin ‘764 or Williams ‘493 or Williams ‘247 or Williams ‘883 or Williams ‘150 or Williams ‘558, combined with Seckel, Schlossauer, and Clavijo-Alvarez (Ans. 7, 10).

Although the Examiner set out the latter rejection as two separate rejections, Appellants rely on the same argument with respect to both rejections (Appeal Br. 12-17), so we will address them together. And, since Appellants base their discussion on Williams ‘569, so will we.

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<sup>8</sup> Martin et al., US 6,610,764 B1, issued Aug. 26, 2003

<sup>9</sup> Williams et al., US 6,838,493 B2, issued Jan. 4, 2005

<sup>10</sup> Williams et al., US 6,867,247 B2, issued Mar. 15, 2005

<sup>11</sup> Williams et al., US 7,179,883 B2, issued Feb. 20, 2007

<sup>12</sup> Williams et al., US 2002/0156150 A1, published Oct. 24, 2002

<sup>13</sup> Williams et al., US 2002/0173558 A1, published Nov. 21, 2002

<sup>14</sup> Martin et al., US 2004/0234576 A1, published Nov. 25, 2004

<sup>15</sup> Rizk, US 2006/0058470, published Mar. 16, 2006

With respect to the rejection based on Hadlock and Martin, the Examiner finds that Hadlock “teaches a nerve regeneration conduit comprising biodegradable polymers select[ed] from polyhydroxyalkanoate (PHA), polyhydroxybutyric acid and polyesters” (Ans. 5) and Martin teaches that poly-4-hydroxybutyrate (P4HB) is a polyhydroxyalkanoate used for tissue regeneration that is more stable than poly-3-hydroxybutyrate (P3HB), which has been used for peripheral nerve regeneration (*id.* at 6). The Examiner concludes that it would have been obvious to make Hadlock’s device from P4HB because “PHA and P3HB have been successfully used for peripheral nerve repair and P4HB is more stable to hydrolysis in tissue engineering” (*id.* at 7).

With respect to the rejections based Williams ‘569 (among others), the Examiner finds that Williams ‘569 discloses “devices of tissue regeneration or nerve guidance/regeneration made of biocompatible polyhydroxyalkanoates (PHA) comprising poly-4-hydroxybutyrate (P4HB)” (Ans. 7) and having pores that range in size from nanometers to 500 µm in diameter (*id.* at 8). The Examiner concludes that Williams ‘569 would have made obvious the device of claim 1 because of the overlapping range of the claimed and disclosed pore sizes (*id.* at 9).

Appellants contend that neither combination of references supports a *prima facie* case of obviousness (Appeal Br. 9-10, 13-15). Appellants also contend that the evidence shows that neural regeneration is, unexpectedly, much faster in nerve conduits made of P4HB than it is in nerve conduits made of P3HB (Appeal Br. 6, 10, 16-17).

The issues with respect to the obviousness rejections are:

Does the evidence provided by Hadlock and Martin, or by Williams '569, support the Examiner's conclusion that the claimed device would have been obvious to a person of ordinary skill in the art? and, if so,

Have Appellants pointed to evidence of unexpectedly superior properties that outweighs the evidence supporting the Examiner's rejection?

*Findings of Fact – Prima facie Obviousness*

1. Hadlock discloses "a nerve regeneration conduit. The conduit includes: a porous biocompatible support . . . in the form of a roll." (*Hadlock* 1: 25-27.)
2. Hadlock discloses that "[i]n some embodiments of the invention, the support 12 is a thin sheet of synthetic polymer. Suitable synthetic polymers include polyhydroxyalkanoates, e.g., polyhydroxybutyric acid" (*id.* at 7: 4-6).
3. Hadlock discloses that the "support . . . can be fabricated using any method known in the art. For example, the use of foam casting for generating prosthetic sheets with varying porosity can be adapted from processes described in" the prior art. (*Id.* at 7: 17-19.)
4. Hadlock discloses that the "pores in the foam should be large enough for exchange of gases and nutrients as necessary for cell maintenance, but small enough so that the surface of the support is impermeable to cells. A typical range suitable for a support of the invention is about 10-100  $\mu\text{m}$ . (*Id.* at 7: 24-27.)
5. Martin discloses that poly-4-hydroxybutyrate (P4HB) "is a homopolymer of 4-hydroxybutyrate (4HB), and belongs to a diverse class of materials called polyhydroxyalkanoates" (Martin, 97).

6. Martin discloses that P4HB “is being developed as a new absorbable material for implantable medical applications. . . . The absorbable biomaterial is strong yet flexible.” (*Id.*, abstract.)
7. Martin suggests that “P4HB should find use in a wide variety of medical fields such as cardiovascular, wound healing, orthopedic, drug delivery, and tissue engineering applications” (*id.*).
8. Martin discloses that “[p]olymerization of 4HB with other hydroxy acids such as 3-hydroxybutyrate (3HB), for example, can yield elastomeric compositions at moderate 4HB contents (20-35%), and relatively hard rigid polymers at lower 4HB contents” (*id.* at 98).
9. Martin discloses that “P3HB is currently being evaluated with some success for use in peripheral nerve repair” (*id.* at 105).
10. Williams ‘569 discloses “[d]evices formed of or including biocompatible polyhydroxyalkanoates . . . with controlled degradation rates. . . . Preferred devices include . . . nerve guides.” (Williams ‘569, abstract.)
11. Williams ‘569 discloses that a “preferred polyhydroxyalkanoate for medical applications is poly-4-hydroxybutyrate (P4HB). P4HB is biocompatible, resorbable, processable, strong and ductile.” (*Id.* at col. 7, ll. 31-33.)
12. Williams ‘569 discloses that the “rate of degradation may also be enhanced by additives which form pores. . . . Pore forming agents are generally added as particulates. . . . The diameters of the particles may suitably be between nanometers to 500 microns.” (*Id.* at col. 10, ll. 27-37.)
13. Williams ‘569 discloses that “[b]iodegradable devices may be used as guides to facilitate the regrowth and reconnection of severed or

damaged nerves and tendons. The devices are generally fabricated as tubes.” (*Id.* at col. 16, ll. 43-45.)

*Principles of Law – Prima facie Obviousness*

“A prima facie case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art.” *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003).

*Analysis – Prima facie Obviousness*

We agree with the Examiner that the cited prior art supports a prima facie case of obviousness. Hadlock discloses a nerve regeneration conduit (FF 1) that can suitably be made from polyhydroxyalkanoates such as polyhydroxybutyrate (FF 2) and should have pores in the size range of 10-100 µm to allow for exchange of nutrients without allowing passage of cells (FF 4). Martin discloses that P4HB is a strong, flexible polyhydroxyalkanoate that is suitable for a wide variety of implantable medical applications (FFs 6-8). Based on these teachings, it would have been obvious to make Hadlock’s nerve regeneration conduit from Martin’s strong, flexible P4HB polymer. The resulting device would meet the limitations of claim 1.

Williams ‘569 discloses that “P4HB is biocompatible, resorbable, processable, strong and ductile” (FF 11) and suitable for making a variety of medical devices, including nerve guides (FF 10), that can include pores having diameters in the size range of nanometers to 500 µm (FF 12). Based on these teachings, it would have been obvious to make a nerve guide from P4HB with pores having diameters in the nanometer-to-500 µm range.

Appellants argue that one would not use the artery repair patch disclosed by Martin, with pores in the range of 180-240  $\mu\text{m}$ , in Hadlock's device because the pores of Martin's patch are outside the size range taught by Hadlock (Appeal Br. 9). This argument is not persuasive because Hadlock teaches that methods were known for varying the porosity of prosthetic sheets (FF 3) and it would have been obvious to use such methods to make Hadlock's nerve regeneration conduit from Martin's P4HB, with pores of the size described by Hadlock.

We have considered Appellants' other arguments regarding the combination of Hadlock and Martin (Appeal Br. 9-10; Reply Br. 7-8). They are adequately addressed above.

Appellants' argument that the references do not suggest a device with pores greater than 5  $\mu\text{m}$  in diameter (Reply Br. 8-9) is unpersuasive because Hadlock discloses that pores of 10-100  $\mu\text{m}$  are suitable for a nerve regeneration conduit (FF 4).

With regard to the *prima facie* case based on Williams '569, Appellants argue that the reference discloses that "the range of pore size is from greater than 0.001 microns to 500 microns. There is no disclosure to select from within this wide pore range to arrive at the narrower pore range of 5-500 microns recited in the claims." (Appeal Br. 14.) This argument is unpersuasive because the size range disclosed in Williams '569 overlaps the size range recited in the claims, and overlapping ranges are *prima facie* obvious. See *In re Peterson*, 315 F.3d at 1329. Appellants' other arguments regarding the Williams '569 patent (Appeal Br. 14-16; Reply Br. 10-12) are adequately addressed above.

*Findings of Fact – Secondary Considerations*

14. Hazari<sup>16</sup> reports an experiment in which a 10 mm segment of the sciatic nerve was resected in Lewis rats and the “gap was bridged using a 14 mm PHB [poly-3-hydroxybutyrate] conduit” (Hazari, 653-654) or with an autologous nerve graft (*id.* at 654, left col.).

15. Hazari discloses that the maximum regeneration distance was measured at 7, 14, and 30 days postoperatively (*id.* at 655, Table 1).

16. Hazari discloses that “[a]t 7 days, axons in the nerve graft had crossed two-thirds of the nerve graft [i.e., 7.62 mm] and in the PHB conduit had penetrated 1.02 mm of the conduit. . . . By 14 days, regenerating axons had reached the distal stump in the nerve grafts, whereas these were almost up to the halfway mark [i.e., 4.35 mm] in PHB conduits.” (*Id.* at 655, right col. and Table 1)

17. Hazari discloses that “[r]egenerating axons grow into the first part of the PHB conduit by 7 days, come up to the halfway mark by 14 days and reach the distal stump by 30 days” (*id.* at 656, right col.).

18. The Specification notes that Hazari<sup>17</sup> “discloses a rate of axonal regeneration using a PHB conduit to bridge a 10 mm nerve gap in a rat sciatic nerve of approx. 10% at 7 days, 50% at 14 days, and complete regeneration at 30 days” (Spec. 2: 30 to 3: 2).

19. The Specification states that, “[d]espite these positive results, it would still be highly desirable to increase the rate of axonal regeneration so

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<sup>16</sup> Hazari et al., *A resorbable nerve conduit as an alternative to nerve autograft in nerve gap repair*, 52 BR. J. PLASTIC SURG. 653-657 (1999).

<sup>17</sup> The Specification incorrectly cites Hazari as appearing in the “British J. Hand Surgery” but the rest of the citation corresponds to the article by Hazari in the British Journal of Plastic Surgery.

that the rate is at least comparable to that obtained using a nerve graft” (Spec. 3: 3-5).

20. The Specification provides a working example in which a 10 mm segment of the sciatic nerve was resected in Sprague-Dawley rats and the nerve endings were bridged with either an autologous nerve graft or one of four types of P4HB conduits (*id.* at 9: 3-10).

21. The Specification states that the distance into the conduits reached by nerve fibers was measured at 10 and 20 days for each group of rats (*id.* at 9: 26-28).

22. The Specification states that “[b]y 10 days, [nerve] fibers were identified in the distal stump of all four PHA4400 [P4HB] conduits indicating that the 10 mm nerve gaps had been bridged. This indicates an axonal regeneration rate of at least 1 mm/day.” (*Id.* at 9: 28-31.)

23. The Specification concludes that “[f]rom these results it is apparent that the rate of axonal regeneration with conduits derived from PHA4400 is faster and significantly improved over those previously reported for PHB conduits” (*id.* at 11: 1-4).

#### *Principles of Law – Secondary Considerations*

“One way for a patent applicant to rebut a *prima facie* case of obviousness is to make a showing of ‘unexpected results,’ i.e., to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected.” *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995).

“The evidence presented to rebut a *prima facie* case of obviousness must be commensurate in scope with the claims to which it pertains.” *In re Dill*, 604 F.2d 1356, 1361 (CCPA 1979).

*Analysis – Secondary Considerations*

We agree with Appellants that the evidence provided in the Specification shows that a nerve conduit made from a P4HB homopolymer provides a rate of nerve regeneration that is significantly superior to that disclosed by Hazari for a P3HB nerve conduit. The Examiner has not provided evidence to show that the difference in the rate of nerve regeneration would have been expected. Therefore, as argued by Appellants (Reply Br. 4), the evidence of unexpected results is sufficient to overcome the Examiner’s rejection of claim 3, which is directed to a device made of P4HB.

Claim 1, however, does not require the device to be made solely of P4HB but encompasses copolymers that include P4HB and any other monomer(s), such as that P3HB/P4HB copolymers discussed by Martin (see FF 8). Appellants’ evidence does not show that copolymers of P4HB in combination with other monomer(s) provide the superior rate of nerve regeneration seen for P4HB relative to P3HB. Appellants’ evidence of unexpected results is therefore not commensurate in scope with claim 1.

*Conclusions of Law*

The evidence provided by Hadlock and Martin, and by Williams ‘569, supports the Examiner’s conclusion that the claimed device would have been obvious to a person of ordinary skill in the art.

Appellants have pointed to evidence of unexpectedly superior properties that outweighs the evidence supporting the Examiner’s rejection of claim 3, but not of claim 1. Claims 4-6 were not argued separately and therefore fall with claim 1. 37 C.F.R. § 41.37(c)(1)(vii).

II.

*Issue*

The Examiner has rejected claims 1 and 3-6 for obviousness-type double patenting based on the claims of Martin ‘764 or Williams ‘493 or Williams ‘569 or Williams ‘247 or Williams ‘883 (Ans. 12).

The Examiner finds that the patented claims are directed to compositions comprising, or devices made from, a polyhydroxyalkanoate comprising 4-hydroxybutyrate (Ans. 12-13). The Examiner concludes that, “[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because the claims recite the same composition comprising a polyhydroxyalkanoate polymer comprising 4-hydroxybutyrate (Ans. 13). The Examiner also concludes that, “although the claims in the issued patent[s] do not specifically recite the pore size between 5-500 $\mu$ m and the shape, the working examples in these issued patents teach conduits and sheets and the pore size, which anticipate the instant claims” (*id.*).

Appellants contend that a rejection for obviousness-type double patenting cannot properly be made based on the cited patents, because they and the present application are not owned by the same company (Appeal Br. 18-20). Appellants also contend that the claims of Martin ‘764 “do not relate to nerve regeneration devices; do not lead one to make a flexible porous nerve regeneration device . . . and therefore do not make obvious the claims of this application” (Appeal Br. 23). Appellants contend that basing the rejection on Williams ‘883 is in error for much the same reason (*id.* at 31). Appellants contend that the claims of Williams ‘493 “relate to rate of degradation of PHA’s in general; not nerve regeneration devices that have an enhanced rate of regeneration” (Appeal Br. 25). Appellants contend that

relying on Williams ‘569 or Williams ‘247 as a basis for the rejection is erroneous for the same reason (*id.* at 27, 29).

The issues with respect to this rejection are: Can a rejection for obviousness-type double patenting properly be based on the cited patents? and, if so,

Does the evidence support the Examiner’s conclusion that the presently claimed device is an obvious variant of the inventions claimed in the cited patents?

*Additional Findings of Fact*

24. Williams ‘493 has a filing date of Feb. 26, 2002, and claims priority under 35 U.S.C. § 120 to March 24, 2000 (Williams ‘493, cover page).

25. Claim 1 of Williams ‘493 is directed to a “device comprising a biodegradable polyhydroxyalkanoate polymer composition that has a controlled degradation rate, under physiological conditions,” where the device loses mass *in vivo* at a specified rate, the degradation rate is manipulated through specified methods, where the polyhydroxyalkanoate polymer has a specified range of average molecular weight, and where the device is selected from specified medical devices that include “nerve guides” (Williams ‘493, col. 38, l. 46 to col. 39, l. 8).

26. Claim 4 of Williams ‘493 is directed to the “device of claim 1 wherein the polyhydroxyalkanoate comprises a polymer selected from the group consisting of poly-4-hydroxybutyrate, poly-4-hydroxybutyrate-co-3-hydroxybutyrate, poly-4-hydroxybutyrate-co-2-hydroxybutyrate, and copolymers and blends thereof” (*id.* at col. 39, ll. 20-25).

27. Claim 24 of Williams ‘493 is directed to the “device of claim 1 comprising pore forming agents” (*id.* at col. 40, ll. 19-20).

28. Williams ‘493 provides a working example that describes preparation of porous P4HB by mixing sodium chloride crystals (80-180  $\mu\text{m}$ ) with molten P4HB, pressing the mixture into a film, and allowing the film to solidify, after which the salt was extracted with water (*id.* at col. 33, ll. 17-26).

29. Williams ‘493 states that “particle size may be adjusted to produce pores of varying size” (*id.* at col. 33, ll. 21-22).

#### *Principles of Law*

“[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.” *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

“Obviousness-type double patenting is a judge-made doctrine that prevents an extension of the patent right beyond the statutory time limit. . . . Its purpose is to prevent an unjustified extension of the term of the right to exclude granted by a patent by allowing a second patent claiming an obvious variant of the same invention to issue to the same owner later.” *In re Berg*, 140 F.3d 1428, 1431 (Fed. Cir. 1998) (citation omitted).

“Because nonstatutory double patenting compares earlier and later claims, an earlier patent’s disclosure is not available to show nonstatutory double patenting. Of course, the earlier patent’s disclosure may register on the patentability scale if that patent qualifies as prior art under 35 U.S.C. § 102.” *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1385 (Fed. Cir. 2003) (citation omitted).

*Analysis*

We agree with Appellants that the Examiner has not adequately explained why the claims on appeal are not patentably distinct from the claims of Martin '764, Williams '569, Williams '247, or Williams '883. The Examiner points out that Martin '764, Williams '569, and Williams '247 claim polyhydroxyalkanoate compositions that can comprise poly-4-hydroxybutyrate (Ans. 12-13). However, the fact that the instantly claimed nerve regeneration device is made from the previously patented composition, without more, is not an adequate basis for concluding that the claimed device is not patentably distinct from the composition per se.

Likewise, while the Examiner points out that Williams '883 is directed to a medical device comprising poly-4-hydroxybutyrate (Ans. 13), the devices encompassed by Williams '883 do not include nerve regeneration devices, and the Examiner has not adequately explained why a nerve regeneration device would be an obvious variant of the devices claimed in Williams '883.

The claims of Williams '493 are another matter. Claim 4 of Williams '493 is directed to a medical device made from a polymer that comprises 4-hydroxybutyrate (FF 26). One of the specific devices claimed is a nerve guide (FF 25). Thus, the only difference between the nerve guide encompassed by Williams '493's claim 4 and the nerve regeneration device of claim 1 on appeal is that the instantly claimed device includes pores 5 to 500 microns in diameter. This variation, however, would have been obvious based on claim 27 of Williams '493, which is directed to devices (including nerve guides) that include pore-forming agents, and the working example of Williams '493, which describes making P4HB with pores of 80-180 microns

in size (FF 28) and states that pores of different sizes can be made using pore-forming particles of different sizes (FF 29). Williams ‘493 qualifies as prior art under 35 U.S.C. § 102(e) (see FF 24), so its disclosure can be considered as evidence of what would have been obvious to a person of ordinary skill in the art.

Appellants argue that a rejection for obviousness-type double patenting based on Williams ‘493 is improper because the application on appeal and Williams ‘493 are not commonly owned (Appeal Br. 24). This argument is not persuasive because a rejection for obviousness-type double patenting is proper when a patent and an application have an inventor in common, even if they are not owned by the same entity. *See* MPEP § 804 (“Double patenting may exist between an issued patent and an application filed by the same inventive entity, or by a different inventive entity having a common inventor, and/or by a common assignee/owner.”); *In re Van Ornum*, 686 F.2d 937 (CCPA 1982) (obviousness-type double patenting rejection affirmed even though application and patent not commonly owned).

Appellants also argue that the claims on appeal are not obvious based on the claims of Williams ‘493 because “[c]laims 1-4 and 6-28 of the ‘493 patent relate to rate of degradation of PHA’s in general; not nerve regeneration devices that have an enhanced rate of regeneration. One skilled in the art would be more likely to look at polymers having a particular rate of degradation and not at the rate of nerve regeneration.” (Appeal Br. 25-26.)

This argument is also unpersuasive. For the reasons discussed above, we conclude that the nerve regeneration device of claim 1 on appeal would

have been an obvious variant of the nerve guides claimed in Williams ‘493. If Appellants are citing the rate of nerve regeneration as evidence of unexpected results, that evidence is not commensurate with the scope of claim 1, as discussed above in the context of obviousness. And, in any event, secondary considerations of nonobviousness cannot be relied on to overcome a rejection for obviousness-type, or nonstatutory, double patenting. *See Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1378 n.1 (Fed. Cir. 2003) (“Obviousness requires inquiry into objective criteria suggesting non-obviousness; nonstatutory double patenting does not.”).

#### *Conclusion of Law*

A rejection for obviousness-type double patenting can properly be based on Williams ‘493, because it has an inventor in common with the present application. The evidence supports the Examiner’s conclusion that the presently claimed device is an obvious variant of the invention claimed in Williams ‘493.

### III.

The Examiner has provisionally rejected claims 1 and 3-6 for obviousness-type double patenting based on the claims of Martin ‘576 or Rizk (Ans. 14).

Appellants point out (Appeal Br. 33-34) that the rejection is based on claims in the Martin ‘576 and Rizk applications that have either been cancelled or withdrawn from consideration. The Examiner argues (Ans. 29-30) that other claims of the cited applications could support the rejection but

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the rejection is not based on those other claims. We therefore reverse the provisional rejection for obviousness-type double patenting.

#### SUMMARY

We reverse the rejections for obviousness-type double patenting based on Martin '764, Williams '569, Williams '247, and Williams '883. We also reverse the provisional obviousness-type double patenting rejection and the obviousness rejections of claim 3.

We affirm the obviousness rejections of claims 1 and 4-6 and the rejection of claims 1 and 3-6 for obviousness-type double patenting based on Williams '493.

#### TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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